

### **REMARKS**

In the amendments above, Claims 2 and 4 have been amended and Claims 1, 13 to 59, and 78 have been cancelled to more particularly point out and distinctly claim Applicants' invention.

#### **35 U.S.C. § 112 Rejections**

Claim 4 has been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner's attention is directed to the amendments above, wherein it is believed that this rejection has been overcome.

#### **35 U.S.C. § 103(a) Rejections**

Claims 2-12, 61, 63-69, 72-74, 76, and 79-83 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Reich et al., U.S. patent No. 5,962,620 ("Reich") in view of Gould et al., U.S. Patent No. 5,120,816 ("Gould"). The Examiner maintains that Reich teaches hydrophilic and hydrophobic polyether polyurethanes; that the polyurethanes may be used to form a shaped structure or device including tubing, catheters, stents, and the like, and the hydrophilic polymers may include drugs and enzymes, and may be coated over the polyurethanes; that Reich further teaches encapsulation of drugs in preferably, high viscosity hydrophilic polymers; that Reich also teaches the specific polymer polyurethane polycarbonate; that the polyether polyurethanes can also be formed into spreadable foams, gels and films; that Reich is silent to the limitation "foam" in regards to the scaffold; that Gould teaches that it is well known that water in a polyurethane precursor formation can cause foaming during polymerization, and that water in a hydrophobic polyurethane precursor formulation can assist in producing foams ranging from flexible to rigid; that it is well within the skilled artisan to optimize a composition (MPEP 2144.05(II)). The Examiner maintains that one

of ordinary skill in the art would have been motivated to modify the amount of water during polymerization in order to produce a foamed substrate to the desired specifications and properties including compressibility and porosity; that, furthermore, the limitations set out in claims 79-83 appear to all be dependent upon the degree of foaming that takes place, that is, pores size and void volume; that about unexpected results, a practitioner would have reasonably expected a foamed hydrophobic polyurethane scaffold; and that it would have been obvious to one of ordinary skill in the art to include the limitation "foam" as suggested by Gould.

Applicants respectfully traverse the rejections.

The invention described and claimed herein is directed to an implant for delivering therapeutic agents, which implant comprises a resilient or flexible elastomeric foam matrix scaffold having a hydrophilic coating. It is noteworthy that the scaffold is reticulated, i.e., it comprises interconnected or intercommunicating voids or pores. See, for example, Claims 2 and 79-83. Moreover, the scaffold is at least partially hydrophobic, and the coating contains one or more therapeutic agents to be released within a patient.

As the Examiner pointed out, Reich discloses hydrophilic or hydrophobic polyester polyurethane substrates that may optionally have a coating. However, Reich's substrates differ in that they are either solid or liquid thermoset compositions (see, for example, Column 3, lines 45-46, Column 4, lines 5-14 and 59-61, and Column 5, lines 49-50), not the resilient or flexible reticulated substrates required according to Applicants' invention.

With regard to Gould, Applicants respectfully point out that Gould is completely silent as to the formation of a foam scaffold that has a series of interconnected pores. The subject application, as filed, discloses on paragraph [0128] a "porous biodurable

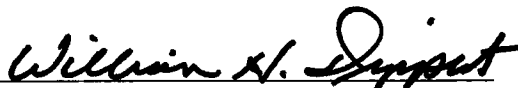
elastomeric matrix" that is "considered to be reticulated because its microstructure comprises interconnected open pores bounded by the configuration of the struts and intersections that constitute a solid structure." Nothing in Gould teaches or suggests a reticulated foam scaffold as taught by Claims 2 and 79-83. A person of ordinary skill in the art would not achieve the subject invention through the combination of Reich and Gould.

Applicants submit that the claims herein are patentable over Reich in view of Gould. Therefore, Applicants respectfully request the Examiner reconsider and withdraw the rejections under 35 U.S.C. §103.

Reconsideration and allowance of all the claims herein are respectfully requested.

Respectfully submitted,

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